DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0045]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Health and Diet Survey—ZOO4 Supplement

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [*insert date 30 days after date of publication in the* **Federal Register].**

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

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SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. **3507,** FDA has submitted the following proposed collection of information to OMB for review and clearance.

Health and Diet Survey—ZOO4 Supplement

The authority for FDA to collect the information derives from the FDA commissioner's authority, as specified in section 903(d)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(d)(2)). The "Health and Diet Survey—2004 Supplement" will provide FDA with information about consumers' knowledge of dietary fats and the risk of coronary heart disease as well as consumers' attitudes toward diet, health, and physical activity. A total of 2,200 adults in the 50 States and the District of Columbia will be interviewed by telephone. Participation will be voluntary. The survey will collect information concerning the following items: (1) Knowledge of the relationships between the risk of heart disease and dietary fats, including saturated fat, trans fatty acids, hydrogenated oil, omega-3 fatty acids, monounsaturated fats, and polyunsaturated fats; (2) attitudes toward diet, health, and physical activity; and (3) demographics and health status.

The agency has established specific targets to improve consumer understanding of diet-disease relationships, and in particular, the relationships between dietary fats and the risk of coronary heart disease, the leading cause of death in the United States. FDA intends to evaluate and track consumer understanding of heart-healthy and heart-harmful fats (saturated fat, trans fatty acids, and omega-3 fatty acids) as initial outcome measures of its achievement in improving public health. The primary purpose of the information collected in the survey will be to gauge current levels of consumer understanding. The establishment of a baseline of consumer understanding will be useful for the

development of performance indicators to identify and measure incremental improvement in consumer understanding. A secondary purpose of the information will be to increase the agency's understanding of consumers' attitudes toward diet, health, and physical activity. This information will provide insight for the exploration of effective communication strategies and messages to assist consumers in making informed dietary and lifestyle choices.

In the **Federal Register** of February 18, 2004 **(69** FR 7642), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN'

Activity	Number of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Pretest	27	1	27	0.5	13.5
Screener	6,000	1	6,000	0.02	120
Survey	2,000	1	2,000	0.17	340
Survey ("initial refuses")	200	1	200	0.08	16
Total					490

[1] There are no capital costs or maintenance and operating costs for this collection of information.

These estimates are based on FDA's experience with previous consumer surveys. Prior to the administration of the survey, the agency plans to conduct a pretest of the final questionnaire to examine and reduce potential problems in survey administration The pretest will be conducted in three waves, each with nine respondents. The agency will use a screener to select an eligible adult respondent in each household to participate in the survey. Target sample size **of** the survey is 2,000 respondents who complete the interview. The agency, as part of an effort to increase survey participation, plans to re-contact and **complete** the interview with prospective respondents who refuse to participate at initial contacts. Two hundred of those who refuse for the second time, defined as "initial refusers," will be administered **a** shorter interview

about their knowledge of saturated fat, trans fatty acids, omega-3 fatty acids, and the **risk** of coronary heart disease.

Dated: 5-12-04

May 12, *2004.*

William Hubbard

William K. Hubbard,
Associate Commissioner for **Policy and Planning.**

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